REMARKS

Status of the Claims

Claims 5-7 and 15 were rejected. Claims 5-7 and 15 remain pending.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner rejected claims 5-7 and 15 under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not provide an enabling disclosure for these claims. Claim 15 recites a vaccine comprising SEQ ID NO:4. The Examiner maintains the enablement rejection as it "is not clear from Applicants arguments that SEQ ID NO:4 would be protective against the R6x serotype or the Type 4 serotype" (Page 9, lines 5-7 of January 25, 2008 Office Action.) This rejection is respectfully traversed.

In view of the comments appearing in the Office Action of January 25, 2008, it appears the Examiner's rejection for lack of enablement is based on a misunderstanding of the pending claim scope. Page 11, lines 1-2 of the 1/25/08 Office Action states "the breath of the claims is quite broad in view of the scope of the possible polypeptides as well as the scope of the pneumococcal infections." Further page 9, lines 12-14 of the 1/25/08 Office Action states "the broad scope of claims which encompass all variants of the polypeptide and the possibility of changing one or more amino acids to any one of 23 different amino acids..." These comments are not relevant to enablement in view of pending claim 15, which is drawn to a vaccine "comprising SEQ ID NO:4, wherein said polypeptide does not bind choline..." and is "effective for treating or protecting against R6x pneumococcal infection or Type 4 pneumococcal infection." Thus, the reasoning for lack of enablement asserted by the Examiner is not based on the pending claims. The Examiner is respectfully requested to review the pending claims in view of the evidence regarding enablement outlined below.

Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention

without "undue experimentation." *In re* Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re* Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). In light of this standard, points A-E below provide evidence regarding the objective enablement of the instant claims.

A. SEQ ID NO:3 (R1, derived from Streptococcus pneumoniae serotype 4) provided active immunization mice challenged with Streptococcus pneumoniae serotype 6B. 80% of the mice immunized with SEQ ID NO:3 survived the challenge. See, Example 3. *Note this demonstrates a cross-protective effect to serotype 6B, when the vaccine polypeptide was derived from serotype 4*. This cross protecting effect is significant and discussed further in point C below.

B. As illustrated in Figure 2 of the specification and in Appendix 1 (provide in response to Office Action filed 1/11/07), the N-terminal choline binding proteins comprise two alpha helical domains referred to as Domain A and Domain C. As outlined above, the specification provides data demonstrating that SEQ ID NO:3 (referred to as R1) provides protection against serotype R6X.

C. The cross protective effect for SEQ ID NO:3 (from serotype 4) to produce an immune response to the R6X isolate is significant. In fact, Domain A of the R6X isolate (SEQ ID NO:9) and Domain A of the serotype 4 (SEQ ID NO:3) share only 55% identity (see Appendix 2, submitted with response to Office Action mailed 1/11/07), *yet a protective effect on the R6X serotype was produced upon administration of Domain A from serotype 4*.

D. The claims of the present invention recite SEQ ID NO:4. As SEQ ID NO:4 possesses a significantly higher degree of structural similarity to SEQ ID NO:3 than that of SEQ

ID NO:9, one of skill in the art would conclude that the success of SEQ ID NO:3 for cross protecting against the R6x serotype renders probable the ability of SEQ ID NO: 4 (as claimed by the present invention) to also produce a protective effect.

E. SEQ ID NO:3 is longer than SEQ ID NO:4. SEQ ID NO:3 comprises the following 3 regions: 1) an N-terminal region; 2) Domain A; and 3) Domain B. (See, Appendix 1 filed with response of 1/11/07.) SEQ ID NO:4 comprises Domain C which shares 96% similarity to Domain A. The additional sequences found in SEQ ID NO:3 on the N-terminal side share only 29% sequence identity to the corresponding region of the CbpA protein from serotype R6x. The additional sequences found in SEQ ID NO:3 on the C-terminal side (Domain B) share only 6% sequence identity to the corresponding region of the CbpA protein from serotype 6. Given that SEQ ID NO:3 (derived from serotype 4) was shown to provide a protective effect against serotype R6x, such an effect would occur via *conserved epitopes* shared between the CbpA proteins from both serotypes. Domain A in SEQ ID NO:3 shares 96% similarity to SEQ ID NO:4 and thus contains a significant degree of structural similarity, when compared to the additional 2 domains contained in SEQ ID NO:3 (i.e., 29% identity and 6% identity).

F. The art cited the Examiner, further supports Applicants position of enablement. Specifically, the importance of sequence conservation is further support by Bogaert *et al.* (2004) *Vaccine* 22:2209-220 (cited by the Examiner in the 10/11/06 Office Action). In discussing PspC based vaccines Bogaert *et al.* conclude that "Importantly, these proteins [PspC] appear to be highly conserved among pneumococcal strains, implicating a potential broad [immunogenic] coverage" (page 2215, column 2, lines 9-11).

Thus, in light of the structural and functional studies performed and the state of the art, as summarized above in items A-F, one of skill in the art would accept that SEQ ID NO:4 would

provide a protective effect against both the R6x serotype and the Type 4 serotype as recited in the instant claims. Thus, in view of the data in the specification, the structural relationship between SEQ ID NO: 3 and 4, and the state of art, claims 5, 6, 7 and 15 are enabled.

CONCLUSION

It is submitted that this application is ready for allowance. In view of the above amendments and remarks, the Examiner is respectfully requested to withdraw the rejections and allow claims 5, 6, 7, and 15.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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